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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,603	07/12/2001	Jennifer L. Hillman	PF-0211-2 DIV	4380

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,603	HILLMAN ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,10,11,30 and 43-57* is/are pending in the application.

4a) Of the above claim(s) *1,2,11,43-45,47,49,50 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,30,46,48,51,52 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed November 28, 2003 has been received and entered. Claims 1-2, 10-11, 30 and 43-57 are pending in the instant application, of which claims 1-2, 11, 43-45, 47, 49, 50 and 53 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 10, 30, 46, 48, 51-52 and 54-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The claims are directed to isolated antibodies which specifically bind to a polypeptide comprising SEQ ID NO: 1 or polypeptides comprising naturally occurring amino acid sequences at least 90% identical to SEQ ID NO: 1 or fragments of a polypeptide having the amino acid sequence of SEQ ID NO: 1, said fragments bind to microtubules.

Applicants are asserting that variants, and in particular, naturally occurring variants, at least 90% identical to SEQ ID NO: 1, are described at page 11, lines 14-17. Applicants further assert that the chemical and structural features of hLC3 are described, for example, on page 11, lines 6-11. Applicants conclude that one of ordinary skill in the art would recognize polypeptide sequences that are naturally occurring variants at least 90% identical to SEQ ID NO: 1, and that bind to microtubules, since it would be routine to determine whether such a variant of SEQ ID NO: 1 had hLC3 activity using the disclosed assay (Specification page 46).

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that variants, and in particular, naturally occurring variants, at least 90% identical to SEQ ID NO: 1, are described at page 11, lines 14-17. However, Applicants description is merely a statement that things 90% identical to SEQ ID NO: 1 are encompassed. The genus claim is supported by a single working example, and therefore is not an adequate written description of the genus claims.

Second, Applicants assert that the chemical and structural features of hLC3 are described, for example, on page 11, lines 6-11. However, again Applicants teachings are limited to a single disclosed example (SEQ ID NO: 1). A single disclosed example simply does not provide the necessary written description support for a genus claim.

Finally, Applicants conclude that one of ordinary skill in the art would recognize polypeptide sequences that are naturally occurring variants at least 90% identical to SEQ ID NO: 1, and that bind to microtubules, since it would be routine to determine whether such a variant of SEQ ID NO: 1 had hLC3 activity using the disclosed assay (Specification page 46). However, Applicants appear to arguing that their invention is enabled, not adequately described. Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision. Again, a single working example is not commensurate in scope with the claimed genus claims.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural

variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "SEQ ID NO: 1" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a

representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

2. The rejection of claims 10, 46, 48, 51-52 and 54-57 under 35 U.S.C. 102(b) as being anticipated by Mann et al is maintained.

Applicants are asserting that if an antibody binds to rat light chain 3 (LC3) then it falls outside the scope of the claims since claim 10 requires it to bind specifically only to recited polypeptides. Applicants further assert that the Examiner has not shown that the 34 amino acid fragment of rat LC3 would be sufficient to bind microtubules.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, are asserting that if an antibody binds to rat light chain 3 (LC3) then it falls outside the scope of the claims since claim 10 requires it to bind specifically only to

recited polypeptides. However, Applicants are respectfully directed back to their own claim language. The claims require that the isolated antibody specifically binds to "a fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1, said fragment binds to microtubules." Clearly, 34 consecutive amino acids can be construed as a "fragment of SEQ ID NO: 1." Furthermore, Mann et al (Journal of Neuroscience Research Vol. 43, No. 5, pp 535-544, March 1, 1996) (Submitted as IDS reference number 9 by Applicants) sets forth that rat "LC3 is a component of both the MAP1A and MAP1B microtubule binding domains." (See abstract). Accordingly, the antibody disclosed by Mann et al is deemed to anticipate the claimed invention.

Mann et al (Journal of Biological Chemistry Vol. 269, No. 15, pp 11492-11497) disclose of anti LC3 antiserum which specifically binds to light chain 3, a subunit of the neuronal microtubule-associated proteins, MAP1A and MAP1B. Mann et al set forth of the sequence of LC3 in Figure 4. This figure contains 34 consecutive amino acids in common with SEQ ID NO: 1 of the instant invention, as well as an 83.4% overall match.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 103

3. The rejection of claims 10, 30, 46, 48, 51-52, and 54-57 under 35 U.S.C. 103(a) as being unpatentable over Mann et al in view of Queen et al is maintained.

Applicants arguments are identical to the assertions made in paragraph number 2 above, and have been fully addressed in paragraph number 2.

For reasons of record, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
February 23, 2004